K061422

Non-Confidential Summary of Safety and Effectiveness

22-May-06

SEP 25 2006

Austin Medical, Inc.
1578 Prairie Road
Enterprise, FL 32725

Tel – (407) 549-5643
Fax – (828) 586-1093

Official Contact: Tim Hutto, Owner

Proprietary or Trade Name: Surgical Drapes

Common/Usual Name: Surgical Drapes

Classification Name: Surgical drapes

Device: Various types of surgical drapes

Predicate Devices: Webster Enterprises – K864899

Device Description:

Austin Medical offers a series of non-sterile surgical drapes for various surgical procedure applications, i.e., table covers, OB/GYN, General Surgery, Orthopedic, ENT and ENNT, Drape Sheets, Cystoscopy, Craniotomy, Angiography, Fluid Pouches, Instrument Covers, U Drapes, Minor procedure drapes, and pediatric drapes.

Indications for Use:

Indicated Use --	Non-sterile surgical drapes made from natural and synthetic materials intended to be used by medical professionals as protective coverings, such as a patient covering to isolate a site for surgical incision from contamination. These are provided non-sterile to kit packers, who then may sterilize the drape as ~~part of a kit.~~
Patient Population --	Any individual
Environment of Use --	Physician office, hospital, sub-acute institutions
Contraindications --	None

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Device Attributes:

Features	Predicate Webster – K864899	Austin Proposed
Indications for use	Surgical drapes made from natural and synthetic materials intended to be used by medical professionals as protective coverings, such as a patient covering to isolate a site for surgical incision from contamination	Same
Environment of Use	Physician offices, Hospital, Sub-acute Institutions	Same
Patient Population	No limitations	Same
Contraindications	None	None
Sterility	Non-sterile Sterile	Non-sterile
Configurations	Many	Many
Absorbency	Absorbent and non-absorbent	Same
Materials in patient contact	Micro-embossed LDPE, Clear LDPE, Sontara, non-woven, Airtex, Polyfoam, Medical grade tape, liners	Identical
Disposable	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

The Austin Medical surgical drapes are viewed as substantially equivalent to the following predicate device, Webster, K864899.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2006

Austin Medical, Incorporated
Mr. Paul E. Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court # 102
Bonita Springs, Florida 34134-2015

Re: K061422
Trade/Device Name: Surgical Drapes
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKK
Dated: September 14, 2006
Received: September 15, 2006

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K061422 (To be assigned)

Device Name:

Surgical Drapes. Various disposable, non-sterile surgical drapes (Table covers, OB/GYN, General Surgery, Orthopedic, ENT and ENNT, Drape Sheets, Cystoscopy, Craniotomy, Angiography, Field Pouches, and Instrument Covers)

Indications for Use:

Surgical drapes made from natural and synthetic materials intended to be used by medical professionals as protective coverings, such as a patient covering to isolate a site for surgical incision from contamination. These are provided non-sterile to kit packers, who then may sterilize the drape as part of a kit.

Prescription Use X (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
n of Anesthesiology, General Hospital,
ion Control, Dental Devices
Number: K061422